UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
***Milanesi et. al v. C.R. Bard*,**
Case No. 2:18-cv-01320

MOTIONS IN LIMINE OPINION AND ORDER NO. 43

Defendants' Motion *in Limine* ("MIL") No. 11 and Plaintiffs' MIL No. 9

This matter comes before the Court on (i) C.R. Bard, Inc. ("Bard") and Davol Inc.'s ("Davol") (collectively, "Defendants") MIL No. 11 to Exclude Evidence and Argument Concerning the Later Switch from a PET Ring to a PDO Ring in the Ventralex, (ECF No. 183), which Plaintiffs Antonio Milanesi and Alicia Morz de Milanesi ("Plaintiffs" or "the Milanesi's") oppose, (ECF No. 260), and (ii) Plaintiffs' MIL No. 9 to Exclude any Evidence or Argument that Ventralex Patch or Any Other "Ventralex" Product Have Never Been Recalled by the FDA, (ECF No. 210), which Defendants' oppose. (ECF No. 223.)

For the reasons stated herein, the Court **GRANTS IN PART** and **DENIES IN PART** Defendants' MIL No. 11, (ECF No. 183), and **GRANTS IN PART** and **DENIES IN PART** Plaintiffs' MIL No. 9. (ECF No. 210.)

I.[1]

The Milanesi's case will be tried as the second bellwether selected from thousands of cases

[1] For a more complete factual background, the reader is directed to the Court's summary judgment opinion and order in this case *Milanesi v. C.R. Bard*, Case No. 2:18-cv-01320. (ECF No. 167.) All docket citations are to the *Milanesi* case, 2:18-cv-1320, unless otherwise noted.

in this multidistrict litigation ("MDL") titled *In Re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation*, 2:18-md-2846. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (Case No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

The relevant facts here are as follows: The Ventralex hernia patch is a prescription medical device used for umbilical and small ventral hernia repairs. One side of the device contains polypropylene mesh, while the other contains a layer of polytetraflouroethylene ("ePTFE"). The ePTFE side is meant to face and protect the bowel as the device's polypropylene mesh incorporates into the tissue on the opposite side. Inside the device is a "ring" or "memory coil" that is meant to "spring open" so the patch lies flat against the abdominal wall once it is implanted. If that ring were to unintentionally fold inward (*i.e.*, "buckle"), it would risk exposing the bowel to bare polypropylene. This has been known to cause various physical injuries, such as fistulae and adhesions.

The Ventralex patch comes in three sizes: small, medium, and large. This case specifically involves the large Ventralex device, which Bard released in 2006. At that time, the device contained a "ring" that consisted of polyethylene terephthalate ("PET"). This is the version of the device that was implanted in Mr. Milanesi in July of 2007 (the "PET Ventralex"). In July of 2014, Bard changed the material that it used for the large Ventralex ring from PET to a fully absorbable plastic known as polydioxanone ("PDO"). This version of the large device is the only one on the market today.

As noted, on July 11, 2007, Mr. Milanesi underwent surgery to repair what appeared to be a recurrent hernia but was revealed to be a bowel erosion with a fistula and adhesions, which required a bowel resection. Dr. Karanbir Gill, Mr. Milanesi's surgeon, used a large Ventralex hernia patch to repair Mr. Milanesi's injury. Ten years later, on May 25, 2017, Mr. Milanesi was diagnosed with a recurrent entrapped or obstructed ventral incisional hernia. He received emergency surgery the next day. On June 1, 2017, Mr. Milanesi returned for another emergency surgery to remove a high-grade post-operative bowel obstruction caused by "adhesions in the right lower quadrant." Afterwards, Mr. Milanesi developed a recurrent abdominal wall hernia near his previous surgery sites.

Plaintiffs allege that the Mr. Milanesi's injuries resulted from the implantation of the large Ventralex patch. Specifically, they contend that Mr. Milenesi's Ventralex patch "buckled," causing its polypropylene side to adhere to his bowels, leading, in turn, to a high-bowel blockage and, subsequently, multiple hospitalizations. Plaintiffs make three principal allegations to support their claim: (i) that the polypropylene resin used in the Ventralex device "oxidatively degraded" within his body; (ii) that the ePTFE layer of the large Ventralex device contracted more than the polypropylene side, which, in combination with the too-weak memory coil ring, caused the device to "buckle," and (iii) that the Ventralex's ePTFE layer was prone to infection because of its small pore size, which, they assert, was big enough for bacteria to grow in, but too small for white blood cells to enter to intercept the bacteria. Plaintiffs also allege that Bard knew or reasonably should have known that the Ventralex was prone to these alleged problems and marketed and sold it without appropriate warnings. After summary judgment, the following claims remain for trial: defective design (strict liability), failure to warn (strict liability), negligence, gross negligence, negligent misrepresentation, fraud and fraudulent misrepresentation, fraudulent concealment, loss

of consortium, and punitive damages.

Defendants believe Plaintiffs will attempt to introduce evidence concerning Bard's decision to change the Ventralex's ring material from PET to PDO (the "PET-to-PDO ring switch"), as well as evidence concerning the Ventralex's PDO ring in general. They seek to preclude the admission of this evidence under Federal Rules of Evidence 402, 403, 404, and 407. (ECF No. 183.) Simultaneously, Plaintiffs argue that, given the PET-to-PDO ring switch, Rules 402 and 403 prohibit Defendants from arguing that (i) the PET Ventralex or any other "Ventralex" product has "never been recalled by the FDA," and (ii) the PET Ventralex is "still on the market." (ECF No. 210.)

II.

"Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig.*, 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence in advance of trial in order to avoid delay and ensure an evenhanded and expeditious trial." *In re E.I. du Pont De Nemours & Co.*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)). However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—

"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *Ind. Ins. Co*., 326 F. Supp. 2d at 846; *see also Koch*, 2 F. Supp. 2d at 1388. The denial, in whole or in part, of a motion *in limine* does not admit all evidence contemplated by the motion; it simply means that the court cannot adjudicate the motion outside of the trial context. *Ind. Ins Co.*, 326 F. Supp. 2d at 846.

Relevant evidence is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. Evidence that is not relevant is inadmissible. Fed. R. Evid. 402. Relevancy is a threshold test for admissibility. In other words, relevant evidence will still not be admissible if its use would violate another applicable Federal Rule of Evidence. Here, in addition to Rule 402, there are three evidentiary rules at issue: Rules 403, 404, and 407.

Under Rule 403, evidence is not admissible if a court determines that "its probative value is "substantially outweighed by the danger of unfair prejudice, confusion of the issues, misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." Fed. R. Evid. 403. Nor, under Rule 404, will evidence be admitted if it constitutes evidence "of a person's character or character trait"—including "any other crime, wrong, or act"—that is solely introduced to prove said person "acted in accordance" with that character trait at a certain time. Fed. R. Evid. 404. This bar on "character" evidence, however, does not extend to evidence that is introduced for "another purpose, such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident." Fed R. Evid. 404(b).

Likewise, Rule 407 bars the admission of evidence of any "measure" that an alleged tortfeasor takes *after* the manifestation of an "injury or harm" if that measure (i) "would have made

[the] earlier injury or harm less likely to occur" and (ii) is introduced for the purpose of proving the alleged tortfeasor's previous negligence, culpable conduct, production of a defective product, or failure to provide an adequate warning. Fed. R. Evid. 407. Such evidence may, however, be introduced for other purposes, including to prove "the feasibility of precautionary measures, if disputed." *Siegel v. Dynamic Cooking Sys, Inc.*, 501 Fed. App'x 397, 405 (6th Cir. 2012).

Evidentiary rulings are made subject to the district court's sound discretion. *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019); *see also Paschal v. Flagstar Bank*, 295 F.3d 565, 576 (6th Cir. 2002) ("In reviewing the trial court's decision for an abuse of discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.").

III.

Defendants, as stated in their MIL No. 11, anticipate that Plaintiffs and their experts may attempt to introduce evidence concerning the PET-to-PDO ring switch and the PDO ring in general. (ECF No. 183 at PageID #13934.) They contend that any evidence related to the PET-to-PDO ring switch or the PDO ring is irrelevant, unduly prejudicial, and/or impermissible evidence of a "subsequent remedial measure". (*Id.* at PageID #13935.) Defendants argue further that any suggestion by Plaintiffs that the Ventralex was "silently" recalled in 2014—*i.e.*, when Bard replaced the device's PET ring with PDO material—would constitute impermissible "character" evidence.

In Plaintiff's MIL No. 9, they ask, *inter alia*, for the Court to preclude Defendants from stating that the PET Ventralex (or any "other" Ventralex device) has never been recalled by the Food and Drug Administration ("FDA") and is still on the market. Plaintiffs contend that the Ventralex, as it was implanted in Mr. Milanesi, is *not* "still on the market" given the fact that it

was updated to contain different ring material. Plaintiffs characterize the ring switch—which invariably required Bard to cease manufacturing and distributing the PET Ventralex—as a "silent recall." (ECF No. 210.)

The Court addresses these motions below based on the evidence they seek to preclude.

A. Evidence Related to the PET-to-PDO Ring Switch and the PDO Ring in General

The ring utilized in the Ventralex large is directly related to the product that was implanted in Mr. Milanesi and is an essential part of Plaintiffs' causation theory. Plaintiffs specifically allege that Defendants *negligently* released the Ventralex large hernia patch with a PET ring that was prone to "buckling" and that the ring did, in fact, "buckle" within Mr. Milanesi, exposing his bowels to bare polypropylene. Now, Plaintiffs partially seek to use evidence of the PET-to-PDO ring switch and the PDO ring to "advance their negligence" claim by showing that Defendants had the "knowledge, opportunity, and intent" to change the Ventralex ring in 2014 for "economic" reasons, rather than to make it safer. (ECF No. 260.)

To the extent Plaintiffs seek to use the aforementioned evidence to prove that Defendants were negligent *before* 2007, it is unclear how such evidence would be relevant *unless* it was used to show that Defendants attempted to fix the PET ring's alleged instability. That, however, would fall within the ambit of Federal Rule of Evidence 407, which explicitly prohibits parties from using evidence of a manufacturer's "subsequent remedial measure" to prove past negligence. Fed. R. Evid. 407.

Plaintiffs also seek to use evidence of the PET-to-PDO ring switch and the PDO ring in general to prove that (i) after Mr. Milanesi was "exposed" to (i.e., implanted with) the Ventralex, Defendants violated their "continuous duty to warn" him of the device's hazardousness, which, in itself, was a form of negligence, and (ii) Defendants acted with "malice, evil intent, and reckless and wanton disregard" for Mr. Milanesi's "health and safety," requiring an assessment of punitive

damages. (ECF No. 291.) The Court intends to issue a separate order that addresses whether this evidence is admissible for the purpose of proving Plaintiffs' post-implantation theories of liability. Thus, here, it does not address the evidence at bar in the context of Plaintiffs "continuing duty to warn" and punitive damages claims.

B. "Lack of Recall" Evidence

Defendants also seek to prevent Plaintiffs from arguing that the PET-to-PDO ring switch constituted a "silent recall." (ECF No. 183.) Simultaneously, Defendants express a clear intention to argue that the Ventralex is "still on the market" and that it has "never been recalled" by the Food and Drug Administration ("FDA"). (ECF No. 223.) Plaintiffs, however, contend that the newer, PDO-based Ventralex that is currently on the market is *not* the same PET-based device that was implanted in Mr. Milanesi. They also argue that, prior to the PET-to-PDO ring switch (*i.e.*, from 2004 to 2016), Bard effectively mooted the FDA's ability to recall the PET Ventralex by (i) marketing the device through the FDA's no-510(k) process and (ii) subsequently failing to report various types of "adverse event" information that related to the device's alleged "buckling" issue.[2] (*Id.*) Thus, according to Plaintiffs, the fact the *current* iteration of the Ventralex is "still on the market" is irrelevant, and, to that end, allowing Defendants to effectively "take credit" for its non-recall would be prejudicially misleading. (ECF No. 210.)

i. **Pre-Ring Switch "Lack of Recall" Evidence**

[2] Specifically, this system entails device manufacturers to report any "adverse event information" regarding one of their products that they "receive or otherwise become aware of . . . from any source" within thirty calendar days after the day the information is received. 21 C.F.R. § 803.50(a). It also requires device manufacturers to report within "5 workdays after the day [they] become aware" that an "[adverse] event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health." 21 C.F.R. § 803.53. This "adverse event information" includes any information that "reasonably suggests" that a manufacturer's device "[m]ay have caused or contributed to a death or serious injury" or "[h] as malfunctioned and this device or a similar device that [they] market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 850.50(a).

The Court confronted a somewhat analogous situation in *Johns*. (*Johns v. C.R. Bard et al.*, Case No. 2:18-cv-01509 ("*Johns*"), ECF No. 359 at PageID #18783.) There, the plaintiff asked the Court to exclude evidence that the "Ventralight ST or other ST products" were "still on the market" because (i) the § 510(k) process Defendants used to market those products did "not address safety," and (ii) Defendants "did not report all adverse event reports known to them" regarding the Ventralight ST to the FDA. (*Id.*) Thus, according to the *Johns* plaintiffs, any "lack of recall" evidence regarding those products was irrelevant and unduly prejudicial, as the FDA essentially never had the ability to determine whether a recall was appropriate in the first place. (*Id.*)

The Court disagreed. For one, it noted that the *Johns* plaintiff's § 510(k) argument "misse[d] the mark" because "[t]he recall process is more relevant to whether a product is *still* permitted to be on the market, rather than the process that *allowed the product to enter the market in the first place*." (*Id.* at PageID #18784) (emphasis added). Accordingly, the Court found that, in the absence of any evidence that Defendants received any "adverse event" information related to the ST products,

> [t]he fact that the ST products are still on the market is relevant to this case. Plaintiff's Utah design defect claims, based on both strict liability and negligence, require evidence of whether the product was "unreasonably dangerous to the user or consumer or to his property," *Brown v. Sears*, *Roebuck & Co*., 328 F.3d 1274, 1279 (10th Cir. 2003) (citing *Ernest W. Hahn, Inc. v. Armco Steel* Co., 601 P.2d 152, 158 (Utah 1979)) (strict liability), or evidence of what Defendants knew or should have known under the circumstances, *see, e.g.*, *Fortune v. Techtronic Indus. N. Am.*, 107 F. Supp. 3d 1199, 1204 (D. Utah 2015) (quoting *Slisze v. Stanley–Bostitch*, 979 P.2d 317, 320 (Utah 1999)) (negligence); *House v. Armour of Am., Inc.*, 929 P.2d 340, 343 (Utah 1996) (strict liability). That the ST products remained on the market is probative of safety because it indicates that the FDA has not had any basis for a recall, such as recurrent death or serious injury. *See* 21 C.F.R. § 803.50(a)(1).

(*Id.* at PageID #18783-84.)

Here, the device at issue (the large PET Ventralex) was, unlike in *Johns*, brought to market through the FDA's no-510(k) preclearance process, which, Plaintiffs point out, did not an entail a

full FDA review of the product's safety features. But that does not mean that the FDA's decision to not recall the PET Ventralex is irrelevant. How the FDA allows a product to enter the market says nothing about its subsequent view on whether the product should stay there. (*See* Johns, ECF No. 359 at PageID #18784.) And, indeed, for the duration the large PET Ventralex remained on the market, the FDA had the power to recall it. *See*, *e.g.*, 21 U.S.C. § 360h(e)(1) (allowing the FDA to issue a mandatory recall of any "device intended for human use" that it finds would "cause serious, adverse health consequences or death"). Accordingly, this part of Plaintiffs' argument is not well taken.

Plaintiffs' additional contention that Bard sat on "adverse event" information related to the PET Ventralex *after* it was marketed also falls short. All of the evidence Plaintiffs cite in support of this assertion came *before* Bard took the PET Ventralex to market, not after. (*See* ECF No. 210 at PageID #14888.) That evidence, in other words, does not demonstrate whether Bard received any reportable "adverse event" information *after* the Ventralex device was released. The Court will no go so far as to assume that Defendants did, in fact, receive such information and chose to withhold it from the FDA.

Here, as in *Johns*, Plaintiffs' manufacturing and design defect claims both require a demonstration that the product was "unreasonably dangerous." (*See* Disp. Mot.'s Order No. 3, ECF No. 167 at PageID #13617, 13621.) Likewise, their gross negligence and punitive damages claims require an express showing that Defendants had "knowledge" or were "aware[] of the imminent danger" that their product posed. (*Id.* at 13635.) Thus, the extent to which the PET Ventralex remained on the market without an FDA recall is "probative of safety," as it suggests the agency did not have "any basis for a recall, such as recurrent death or serious injury." (*Johns*, ECF No. 359 at PageID #18784) (citing 21 C.F.R. § 803.50(a)(1)). Accordingly, this evidence is

admissible.

ii. Post-Ring Switch "Lack of Recall" Evidence

Of course, the probative value of the PET Ventralex's "lack of recall" history is directly related to the length of time that it has been eligible for recall in the first place.[3] This, as noted, is a factual issue that remains in dispute. Plaintiffs contend that the 2014 PET-to-PDO ring switch effectively took the Ventralex device that was implanted in Mr. Milanesi "off" the market because it altered the device's "design" and "mechanics." (ECF No. 210 at PageID #14890.) Defendants, however, contend that the PET- and PDO-based Ventralex's are functionally identical, with the only difference being the newer version's use of an "absorbable" plastic. (*See* Ex. B, Sched. 1, ECF 92-2 at PageID #6540) ("The fundamental scientific technology of the proposed Ventralex Hernia Patch is identical to the currently marketed Ventralex Hernia Patch . . . with the exception of the material type of the recoil ring.").

It seems apparent that, on a superficial level, the older PET Ventralex and the newer, PDO-based Ventralex are different. They do, after all, contain different ring material. Whether or not that material makes any *functional* difference in the device (*i.e.*, by making it more "buckle"-resistant) is, however, unclear. In any event, there is enough dissimilarity for Plaintiffs to make out a colorable claim that the device that was implanted in Mr. Milanesi is no longer "on the market." As discussed above, Plaintiffs cannot make that claim to prove that the PET Ventralex was *originally* defective, as that would run afoul of Rule 407. Nevertheless, should Defendants choose to argue (or even strongly imply) that the device that was implanted in Mr. Milanesi was "still on the market" and/or has "never been recalled" after 2014, they will effectively open the door for Plaintiffs to rebut the assertion with evidence related to the PET-to-PDO ring switch and

[3] It would certainly be misleading, for example, for a manufacturer to claim that one of its products has "never been recalled," even though that same product has not been in distribution for years.

the PDO ring.[4]

IV.

In sum, the Court finds as follows:

1. Federal Rule of Evidence 407 bars Plaintiffs from using evidence related to the PET-to-PDO ring switch or the PDO ring in general to prove either (i) that Defendants negligently issued the PET Ventralex in 2006 or (ii) that the original PET Ventralex was defective. The Court does not opine on the admissibility of the same evidence insofar as it relates to Plaintiffs' post-2007 "continuing duty to warn" or punitive damages claims.
2. Evidence that the Ventralex device was not recalled by the FDA is sufficiently relevant to, and probative of, the product's safety and is, therefore, admissible.
3. There is a clear factual dispute as to whether the Ventralex device that was implanted in Mr. Milanesi remains "on the market" after the PET-to-PDO ring switch.
4. Thus, if Defendants argue—whether explicitly or implicitly—that the Ventralex device that was implanted in Mr. Milanesi is still "on the market" and was "never recalled" *without* specifying that Bard switched the Ventralex's ring material in 2014, Plaintiffs may rebut that contention with evidence of the PET-to-PDO ring switch and the PDO ring in general.

Accordingly, the Court **GRANTS IN PART** and **DENIES IN PART** Defendants' MIL No. 11, (ECF No. 183), and **GRANTS IN PART** and **DENIES IN PART** Plaintiffs' MIL No. 9. (ECF No. 210.)

As with all *in limine* decisions, this ruling is subject to modification should the facts or circumstances at trial differ from that which has been presented in the pre-trial motion and memoranda.

IT IS SO ORDERED.

12/13/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE

[4] This would not, as Defendants contend, constitute the use of impermissible "character" evidence. Rather, Plaintiffs would be using the evidence for the sole purpose of contradicting the assertion that the Ventralex large hernia patch has remained on the market undisturbed since its release.